



Montana Legislative History

Chapter: 768 Session L: 2023

Bill Number: 351 **Senate**

Checklist of Bill History

History and Final Status Sheet	x
Introduced Bill	X
Fiscal Note	N/A
Third Reading Bill	X
Final Version of Bill	X

House

Committee: Energy,
Technology, and
Federal Relations

Hearing Date(s):
[April 5, 2023](#)
[April 7, 2023](#)
(Executive Action)

Senate

Committee: Business, Labor, and Economic
Affairs

Hearing Date(s): [February 24, 2023](#)

Conference Committee

Hearing Date(s): [May 1, 2023](#)

Compiler Notes

Compiled by: smg

Date: Feb. 1, 2023

Notes:

Bill Draft Number: LC1085

Bill Type - Number: SB 351

Short Title: Generally revise privacy laws related to biometric data

Primary Sponsor: Daniel Zolnikov (R) SD 22

Chapter Number: 768

Bill Actions - Current Bill Progress: Became Law

Bill Action Count: 67

Action - Most Recent First	Date	Votes Yes	Votes No	Committee
Chapter Number Assigned	06/07/2023			
(S) Signed by Governor	06/07/2023			
(S) Transmitted to Governor	05/30/2023			
(H) Signed by Speaker	05/27/2023			
(S) Signed by President	05/23/2023			
(C) Printed - Enrolled Version Available	05/16/2023			
(S) Returned from Enrolling	05/16/2023			
(S) Sent to Enrolling	05/16/2023			
(H) 3rd Reading Free Conference Committee Report Adopted	05/02/2023	93	3	
(H) Scheduled for 3rd Reading	05/02/2023			
(S) 3rd Reading Free Conference Committee Report Adopted	05/02/2023	49	1	
(S) 2nd Reading Free Conference Committee Report Adopted	05/02/2023	50	0	
(S) Scheduled for 2nd Reading	05/02/2023			
(H) 2nd Reading Free Conference Committee Report Adopted	05/02/2023	96	2	
(H) Scheduled for 2nd Reading	05/02/2023			
(H) Free Conference Committee Report Received	05/01/2023			
(S) Free Conference Committee Report Received	05/01/2023			
(S) Hearing	05/01/2023			Free Conference Committee on SB 351
(H) Free Conference Committee Appointed	04/26/2023			
(S) Free Conference Committee Appointed	04/24/2023			
(S) Conference Committee Dissolved	04/24/2023			
(S) Conference Committee Appointed	04/21/2023			
(S) 2nd Reading House Amendments Not Concurred	04/20/2023	49	1	
(S) Scheduled for 2nd Reading	04/20/2023			
(H) Returned to Senate with Amendments	04/18/2023			

(H) 3rd Reading Concurred	04/17/2023	97	0
(H) 2nd Reading Concurred	04/14/2023	100	0
(H) Committee Report--Bill Concurred as Amended	04/13/2023		(H) Energy, Technology and Federal Relations
(C) Printed - New Version Available	04/13/2023		
(H) Committee Executive Action--Bill Concurred as Amended	04/07/2023	13	0 (H) Energy, Technology and Federal Relations
(H) Hearing	04/05/2023		(H) Energy, Technology and Federal Relations
(H) First Reading	03/15/2023		
(H) Referred to Committee	03/15/2023		(H) Energy, Technology and Federal Relations
(S) Transmitted to House	03/03/2023		
(S) 3rd Reading Passed	03/02/2023	50	0
(S) Scheduled for 3rd Reading	03/02/2023		
(S) 2nd Reading Passed	03/01/2023	49	0
(S) Scheduled for 2nd Reading	03/01/2023		
(C) Printed - New Version Available	02/25/2023		
(S) Committee Report--Bill Passed as Amended	02/24/2023		(S) Business, Labor, and Economic Affairs
(S) Committee Executive Action--Bill Passed as Amended	02/24/2023	10	0 (S) Business, Labor, and Economic Affairs
(S) Hearing	02/24/2023		(S) Business, Labor, and Economic Affairs
(C) Amendments Available	02/23/2023		
(S) First Reading	02/15/2023		
(S) Referred to Committee	02/15/2023		(S) Business, Labor, and Economic Affairs
(C) Introduced Bill Text Available Electronically	02/15/2023		
(S) Introduced	02/15/2023		
(C) Draft Delivered to Requester	02/15/2023		
(C) Draft Ready for Delivery	02/14/2023		
(C) Executive Director Final Review	02/14/2023		
(C) Draft Ready for Delivery	02/14/2023		
(C) Executive Director Review	02/14/2023		
(C) Executive Director Final Review	01/30/2023		
(C) Executive Director Review	01/30/2023		
(C) Bill Draft Text Available Electronically	01/29/2023		
(C) Draft in Final Drafter Review	01/29/2023		
(C) Draft in Input/Proofing	01/28/2023		
(C) Draft to Drafter - Edit Review	01/25/2023		
(C) Draft in Edit	01/18/2023		
(C) Draft in Legal Review	01/18/2023		
(C) Draft to Requester for Review	01/18/2023		
(C) Draft to Requester for Review	01/17/2023		

(C) Draft to Requester for Review	01/13/2023
(C) Draft to Requester for Review	01/03/2023
(C) Draft Taken Off Hold	01/02/2023
(C) Draft On Hold	11/23/2022
(C) Draft Request Received	11/13/2022

Sponsor, etc.

Sponsor, etc.	Last Name/Organization	First Name Mi
Requester	Zolnikov	Daniel
Drafter	Sullivan	Erin
Primary Sponsor	Zolnikov	Daniel

Subjects

Description	Revenue/Approp.	Vote Majority Req.	Subject Code
Consumer Protection		Simple	CONS
Privacy		Simple	PRIV

Additional Bill Information

Fiscal Note Probable: No

Preintroduction Required: N

Session Law Ch. Number: 768

DEADLINE

Category: General Bills

Transmittal Date: 03/03/2023

Return (with 2nd house amendments) Date: 04/18/2023

Section Effective Dates

Section(s)	Effective Date	Date Qualified
All Sections	01-OCT-23	



AN ACT REVISING LAWS RELATED TO BIOMETRIC PRIVACY; CREATING THE GENETIC INFORMATION PRIVACY ACT; REQUIRING AN ENTITY TO PROVIDE CONSUMER INFORMATION REGARDING THE COLLECTION, USE, AND DISCLOSURE OF GENETIC DATA; PROVIDING FOR LIMITATIONS AND EXCLUSIONS; PROVIDING FOR ENFORCEMENT AUTHORITY; AND PROVIDING DEFINITIONS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Short title. [Sections 1 through 6] may be cited as the "Genetic Information Privacy Act".

Section 2. Definitions. As used in [sections 1 through 6], unless the context clearly indicates otherwise, the following definitions apply:

(1) "Biological sample" means any human material known to contain DNA, including tissue, blood, urine, or saliva.

(2) "Consumer" means an individual who is a resident of this state.

(3) "DNA" means deoxyribonucleic acid.

(4) "Entity" means a partnership, corporation, association, or public or private organization of any character that:

(a) offers consumer genetic testing products or services directly to a consumer; or

(b) collects, uses, or analyzes genetic data.

(5) "Express consent" means a consumer's affirmative response to a clear, meaningful, and prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose.

(6) (a) "Genetic data" means any data, regardless of format, concerning a consumer's genetic characteristics.

(b) The term includes but is not limited to:

- (i) raw sequence data that result from sequencing all or a portion of a consumer's extracted DNA;
- (ii) genotypic and phenotypic information obtained from analyzing a consumer's raw sequence data; and
- (iii) self-reported health information regarding a consumer's health conditions that the consumer provides to an entity that the entity:
 - (A) uses for scientific research or product development; and
 - (B) analyzes in connection with the consumer's raw sequence data.
- (7) "Genetic testing" means:
 - (a) a laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or gene products to determine the presence of genetic characteristics of a consumer; or
 - (b) an interpretation of a consumer's genetic data.
- (8) "Governmental agency" means an executive, legislative, or judicial agency, department, board, commission, authority, institution, or instrumentality of the federal government or of a state or of a county, municipality, or other political subdivision of a state.
- (9) "Person" means an individual, partnership, corporation, association, business, business trust, or legal representative of an organization.
- (10) "Processor" means a person that processes genetic data on behalf of an entity pursuant to a contract between the entity and the processor that prohibits the processor from retaining, using, or disclosing the genetic data, or any information regarding the identity of the consumer, including whether that consumer has solicited or received genetic testing, as applicable, for any purpose other than for the specific purpose of performing the services specified in the contract.
- (11) "Third party" means a person other than the consumer, entity, or processor.

Section 3. Exceptions. (1) [Sections 1 through 6] do not apply to:

- (a) protected health information that is collected by a covered entity or business associate as those terms are defined in 45 CFR, parts 160 and 164, if separate informed consent related to the collection, use, and dissemination of genetic data is obtained from the consumer, parent, guardian, or power of attorney, and the covered entity or business associate follows the policies under [sections 4(6)(a) through (6)(d)];

(b) an entity when it is engaged only in collecting, using, or analyzing genetic data or biological samples in the context of research as defined in 45 CFR 164.501 conducted with the express consent of an individual and in accordance with:

(i) the federal policy for the protection of human research subjects under 45 CFR, part 46, the good clinical practice guideline issued by the international council for harmonisation of technical requirements for pharmaceuticals for human use; or

(ii) the United States food and drug administration policy for the protection of human subjects under 21 CFR, parts 50 and 56; or

(c) uses by a governmental agency.

(2) Beginning June 1, 2025, any collection, storage, use, or dissemination of genetic data by a governmental agency must be performed in accordance with a specific state law or executed through a search warrant.

Section 4. Consumer genetic data -- privacy notice -- consent -- access -- deletion --

destruction. To safeguard the privacy, confidentiality, security, and integrity of a consumer's genetic data, an entity shall:

(1) provide clear and complete information regarding the entity's policies and procedures for the collection, use, or disclosure of genetic data by making available to a consumer:

(a) a high-level privacy policy overview that includes basic, essential information about the entity's collection, use, or disclosure of genetic data; and

(b) a prominent, publicly available privacy notice that includes, at a minimum, information about the entity's data collection, consent, use, access, disclosure, transfer, security, and retention and deletion practices for genetic data;

(2) obtain initial express consent from a consumer, parent, guardian, or power of attorney for the collection, use, or disclosure of the consumer's genetic data that:

(a) clearly describes the entity's use of the genetic data that the entity collects through the entity's genetic testing product or service;

(b) specifies the categories of individuals within the entity that have access to test results; and

- (c) specifies how the entity may share the genetic data;
- (3) if the entity engages in any of the following, obtain a consumer's:
 - (a) separate express consent for:
 - (i) the transfer or disclosure of the consumer's genetic data or biological sample to any third party other than the entity's processors, including the name of the third party to which the consumer's genetic data or biological sample will be transferred or disclosed with the consumer's express consent;
 - (ii) the use of genetic data beyond the primary purpose of the entity's genetic testing product or service and inherent contextual uses; or
 - (iii) the entity's retention of any biological sample provided by the consumer following the entity's completion of the initial testing service requested by the consumer;
 - (b) informed express consent for transfer or disclosure of the consumer's genetic data to third party persons for:
 - (i) research purposes; or
 - (ii) research conducted under the control of the entity for the purpose of publication or generalizable knowledge; and
 - (c) express consent for:
 - (i) marketing to a consumer based on the consumer's genetic data;
 - (ii) marketing by a third-party person to a consumer based on the consumer having ordered or purchased a genetic testing product or service. Marketing does not include the provision of customized content or offers on the websites or through the applications or services provided by the entity with the first-party relationship to the consumer; or
 - (iii) sale or other valuable consideration of the consumer's genetic data.
- (4) comply with the provisions of 44-6-104 requiring a valid legal process for disclosing genetic data to law enforcement or any other government agency without a consumer's express consent;
- (5) develop, implement, and maintain a comprehensive security program to protect a consumer's genetic data against unauthorized access, use, or disclosure; and
- (6) provide a process for a consumer to:
 - (a) access the consumer's genetic data;

- (b) delete the consumer's genetic data;
- (c) revoke any consent provided by the consumer; and
- (d) request and obtain the destruction of the consumer's biological sample.

(7) Genetic data and biometric samples of Montana residents collected in the state may not be stored within the territorial boundaries of any country currently sanctioned in any way by the United States office of foreign asset control or designated as a foreign adversary under 15 CFR 7.4(a). Genetic data or biometric data of Montana residents collected in the state may only be transferred or stored outside the United States with the consent of the resident.

Section 5. Disclosure -- when prohibited -- when express consent required. (1) The disclosure of genetic data pursuant to [sections 1 through 6] must comply with all state and federal laws for the protection of privacy and security.

(2) Notwithstanding any other provisions in [section 4], an entity may not disclose a consumer's genetic data to any entity offering health insurance, life insurance, or long-term care insurance, or to any employer of the consumer without the consumer's express consent.

Section 6. Enforcement. (1) The attorney general has the sole authority to enforce [sections 1 through 6].

(2) The attorney general may initiate a civil enforcement action against a person for violation of [sections 1 through 6].

- (3) In an action to enforce [sections 1 through 6], the attorney general may recover:
- (a) actual damages to the consumer;
 - (b) costs;
 - (c) reasonable attorney fees; and
 - (d) \$2,500 for each violation of [section 4].

Section 7. Codification instruction. [Sections 1 through 6] are intended to be codified as an integral part of Title 30, and the provisions of Title 30 apply to [sections 1 through 6].

- END -

I hereby certify that the within bill,
SB 351, originated in the Senate.

Secretary of the Senate

President of the Senate

Signed this _____ day
of _____, 2023.

Speaker of the House

Signed this _____ day
of _____, 2023.

SENATE BILL NO. 351

INTRODUCED BY D. ZOLNIKOV

AN ACT REVISING LAWS RELATED TO BIOMETRIC PRIVACY; CREATING THE GENETIC INFORMATION PRIVACY ACT; REQUIRING AN ENTITY TO PROVIDE CONSUMER INFORMATION REGARDING THE COLLECTION, USE, AND DISCLOSURE OF GENETIC DATA; PROVIDING FOR LIMITATIONS AND EXCLUSIONS; PROVIDING FOR ENFORCEMENT AUTHORITY; AND PROVIDING DEFINITIONS.

SENATE BILL NO. 351

INTRODUCED BY D. ZOLNIKOV

A BILL FOR AN ACT ENTITLED: "AN ACT REVISING LAWS RELATED TO BIOMETRIC PRIVACY;
CREATING THE GENETIC INFORMATION PRIVACY ACT; REQUIRING A COMPANY TO PROVIDE
CONSUMER INFORMATION REGARDING THE COLLECTION, USE, AND DISCLOSURE OF GENETIC
DATA; PROVIDING FOR LIMITATIONS AND EXCLUSIONS; PROVIDING FOR ENFORCEMENT
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Information Privacy Act".

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indicates otherwise, the following definitions apply:

(1) "Biological sample" means any human material known to contain DNA, including tissue, blood,
urine, or saliva.

(2) (a) "Company" means an entity that:
(i) offers consumer genetic testing products or services directly to a consumer; or
(ii) collects, uses, or analyzes genetic data that resulted from a direct-to-consumer genetic testing
product or service and was provided to the company by a consumer.

(b) The term does not include an entity when it is engaged only in collecting, using, or analyzing
genetic data or biological samples in the context of research as defined in 45 CFR 164.501 conducted in
accordance with the federal policy for the protection of human research subjects under 45 CFR, part 46, the
good clinical practice guideline issued by the international council for harmonisation of technical requirements
for pharmaceuticals for human use, or the United States food and drug administration policy for the protection
of human subjects under 21 CFR, parts 50 and 56.

- 1 (3) "Consumer" means an individual who is a resident of this state.
- 2 (4) "Deidentified data" means data that:
- 3 (a) cannot be reasonably linked to an identifiable individual; and
- 4 (b) is possessed by a company that:
- 5 (i) takes administrative and technical measures to ensure that the data cannot be associated with
- 6 a particular consumer;
- 7 (ii) makes a public commitment to maintain and use data in deidentified form and to not attempt to
- 8 reidentify data; and
- 9 (iii) enters a legally enforceable contractual obligation that prohibits a recipient of the data from
- 10 attempting to reidentify the data.
- 11 (5) "DNA" means deoxyribonucleic acid.
- 12 (6) "Express consent" means a consumer's affirmative response to a clear, meaningful, and
- 13 prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose.
- 14 (7) (a) "Genetic data" means any data, regardless of format, concerning a consumer's genetic
- 15 characteristics.
- 16 (b) The term includes but is not limited to:
- 17 (i) raw sequence data that result from sequencing all or a portion of a consumer's extracted DNA;
- 18 (ii) genotypic and phenotypic information obtained from analyzing a consumer's raw sequence
- 19 data; and
- 20 (iii) self-reported health information regarding a consumer's health conditions that the consumer
- 21 provides to a company that the company:
- 22 (A) uses for scientific research or product development; and
- 23 (B) analyzes in connection with the consumer's raw sequence data.
- 24 (c) The term does not include deidentified data.
- 25 (8) "Genetic testing" means:
- 26 (a) a laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or
- 27 gene products to determine the presence of genetic characteristics of a consumer; or
- 28 (b) an interpretation of a consumer's genetic data.

(9) "Person" means an individual, partnership, corporation, association, business, business trust, or legal representative of an organization.

NEW SECTION. Section 3. Limitations. [Sections 1 through 6] do not apply to protected health information that is collected by a covered entity or business associate as those terms are defined in 45 CFR, parts 160 and 164.

NEW SECTION. Section 4. Consumer genetic data -- privacy notice -- consent -- access -- deletion -- destruction. To safeguard the privacy, confidentiality, security, and integrity of a consumer's genetic data, a company shall:

(1) provide clear and complete information regarding the company's policies and procedures for the collection, use, or disclosure of genetic data by making available to a consumer:

(a) a high-level privacy policy overview that includes basic, essential information about the company's collection, use, or disclosure of genetic data; and

(b) a prominent, publicly available privacy notice that includes, at a minimum, information about the company's data collection, consent, use, access, disclosure, transfer, security, and retention and deletion practices;

(2) obtain a consumer's initial express consent for the collection, use, or disclosure of the consumer's genetic data that:

(a) clearly describes the company's use of the genetic data that the company collects through the company's genetic testing product or service;

(b) specifies who has access to test results; and

(c) specifies how the company may share the genetic data;

(3) if the company engages in any of the following, obtain a consumer's:

(a) separate express consent for:

(i) the transfer or disclosure of the consumer's genetic data to any person other than the company's vendors and service providers;

(ii) the use of genetic data beyond the primary purpose of the company's genetic testing product or

1 service and inherent contextual uses; or

2 (iii) the company's retention of any biological sample provided by the consumer following the
3 company's completion of the initial testing service requested by the consumer;

4 (b) informed consent in accordance with the federal policy for the protection of human research
5 subjects under 45 CFR, part 46, for transfer or disclosure of the consumer's genetic data to third party persons
6 for:

7 (i) research purposes; or

8 (ii) research conducted under the control of the company for the purpose of publication or
9 generalizable knowledge; and

10 (c) express consent for:

11 (i) marketing to a consumer based on the consumer's genetic data; or

12 (ii) marketing by a third-party person to a consumer based on the consumer having ordered or
13 purchased a genetic testing product or service. Marketing does not include the provision of customized content
14 or offers on the websites or through the applications or services provided by the company with the first-party
15 relationship to the customer.

16 (4) comply with the provisions of 44-6-104 requiring a valid legal process for disclosing genetic
17 data to law enforcement or any other government agency without a consumer's express written consent;

18 (5) develop, implement, and maintain a comprehensive security program to protect a consumer's
19 genetic data against unauthorized access, use, or disclosure; and

20 (6) provide a process for a consumer to:

21 (a) access the consumer's genetic data;

22 (b) delete the consumer's genetic data; and

23 (c) request and obtain the destruction of the consumer's biological sample.

24

25 **NEW SECTION. Section 5. Disclosure -- when prohibited -- when written consent required. (1)**

26 The disclosure of genetic data pursuant to [sections 1 through 6] must comply with all state and federal laws for
27 the protection of privacy and security.

28 (2) [Sections 1 through 6] may not apply to protected health information that is collected by a

1 covered entity or business associate governed by the privacy, security, and breach notification rules issued by
2 the:

3 (a) United States department of health and human services, 45 CFR, parts 160 and 164,
4 established pursuant to the federal Health Insurance Portability and Accountability Act of 1996; and

5 (b) federal Health Information Technology for Economic and Clinical Health Act of 2009.

6 (3) Notwithstanding any other provisions in [section 4], a company may not disclose a consumer's
7 genetic data to any entity offering health insurance, life insurance, or long-term care insurance, or to any
8 employer of the consumer without the consumer's written consent.

9
10 NEW SECTION. Section 6. Enforcement. (1) The attorney general may enforce [sections 1 through
11 6].

12 (2) The attorney general may initiate a civil enforcement action against a person for violation of
13 [sections 1 through 6].

14 (3) In an action to enforce [sections 1 through 6], the attorney general may recover:

15 (a) actual damages to the consumer;

16 (b) costs;

17 (c) reasonable attorney fees; and

18 (d) \$2,500 for each violation of [section 4].

19

20 NEW SECTION. Section 7. Codification instruction. [Sections 1 through 6] are intended to be
21 codified as an integral part of Title 30, and the provisions of Title 30 apply to [sections 1 through 6].

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(ii) collects, uses, or analyzes genetic data that resulted from a direct-to-consumer genetic testing
product or service and was provided to the company by a consumer.

(b) The term does not include an entity when it is engaged only in collecting, using, or analyzing
genetic data or biological samples in the context of research as defined in 45 CFR 164.501 conducted in
accordance with the federal policy for the protection of human research subjects under 45 CFR, part 46, the
good clinical practice guideline issued by the international council for harmonisation of technical requirements
for pharmaceuticals for human use, or the United States food and drug administration policy for the protection
of human subjects under 21 CFR, parts 50 and 56.

- 1 (3) "Consumer" means an individual who is a resident of this state.
- 2 (4) "Deidentified data" means data that:
- 3 (a) cannot be reasonably linked to an identifiable individual; and
- 4 (b) is possessed by a company that:
- 5 (i) takes administrative and technical measures to ensure that the data cannot be associated with
- 6 a particular consumer;
- 7 (ii) makes a public commitment to maintain and use data in deidentified form and to not attempt to
- 8 reidentify data; and
- 9 (iii) enters a legally enforceable contractual obligation that prohibits a recipient of the data from
- 10 attempting to reidentify the data.
- 11 (5) "DNA" means deoxyribonucleic acid.
- 12 (6) "Express consent" means a consumer's affirmative response to a clear, meaningful, and
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- 26 (a) a laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or
- 27 gene products to determine the presence of genetic characteristics of a consumer; or
- 28 (b) an interpretation of a consumer's genetic data.

(9) "Person" means an individual, partnership, corporation, association, business, business trust, or legal representative of an organization.

NEW SECTION. Section 3. Limitations. [Sections 1 through 6] do not apply to protected health information that is collected by a covered entity or business associate as those terms are defined in 45 CFR, parts 160 and 164.

NEW SECTION. Section 4. Consumer genetic data -- privacy notice -- consent -- access -- deletion -- destruction. To safeguard the privacy, confidentiality, security, and integrity of a consumer's genetic data, a company shall:

(1) provide clear and complete information regarding the company's policies and procedures for the collection, use, or disclosure of genetic data by making available to a consumer:

(a) a high-level privacy policy overview that includes basic, essential information about the company's collection, use, or disclosure of genetic data; and

(b) a prominent, publicly available privacy notice that includes, at a minimum, information about the company's data collection, consent, use, access, disclosure, transfer, security, and retention and deletion practices;

(2) obtain a consumer's initial express consent for the collection, use, or disclosure of the consumer's genetic data that:

(a) clearly describes the company's use of the genetic data that the company collects through the company's genetic testing product or service;

(b) specifies who has access to test results; and

(c) specifies how the company may share the genetic data;

(3) if the company engages in any of the following, obtain a consumer's:

(a) separate express consent for:

(i) the transfer or disclosure of the consumer's genetic data to any person other than the company's vendors and service providers;

(ii) the use of genetic data beyond the primary purpose of the company's genetic testing product or

service and inherent contextual uses; or

(iii) the company's retention of any biological sample provided by the consumer following the company's completion of the initial testing service requested by the consumer;

(b) informed consent in accordance with the federal policy for the protection of human research subjects under 45 CFR, part 46, for transfer or disclosure of the consumer's genetic data to third party persons for:

(i) research purposes; or

(ii) research conducted under the control of the company for the purpose of publication or generalizable knowledge; and

(c) express consent for:

(i) marketing to a consumer based on the consumer's genetic data; or

(ii) marketing by a third-party person to a consumer based on the consumer having ordered or purchased a genetic testing product or service. Marketing does not include the provision of customized content or offers on the websites or through the applications or services provided by the company with the first-party relationship to the customer.

(4) comply with the provisions of 44-6-104 requiring a valid legal process for disclosing genetic data to law enforcement or any other government agency without a consumer's express written consent;

(5) develop, implement, and maintain a comprehensive security program to protect a consumer's genetic data against unauthorized access, use, or disclosure; and

(6) provide a process for a consumer to:

(a) access the consumer's genetic data;

(b) delete the consumer's genetic data; and

(c) request and obtain the destruction of the consumer's biological sample.

NEW SECTION. Section 5. Disclosure -- when prohibited -- when written consent required. (1)

The disclosure of genetic data pursuant to [sections 1 through 6] must comply with all state and federal laws for the protection of privacy and security.

(2) [Sections 1 through 6] may not apply to protected health information that is collected by a

1 covered entity or business associate governed by the privacy, security, and breach notification rules issued by
2 the:

3 (a) United States department of health and human services, 45 CFR, parts 160 and 164,
4 established pursuant to the federal Health Insurance Portability and Accountability Act of 1996; and

5 (b) federal Health Information Technology for Economic and Clinical Health Act of 2009.

6 (3) Notwithstanding any other provisions in [section 4], a company ~~may~~ HAS THE SOLE AUTHORITY TO
7 not disclose a consumer's genetic data to any entity offering health insurance, life insurance, or long-term care
8 insurance, or to any employer of the consumer without the consumer's written consent.

9
10 NEW SECTION. Section 6. Enforcement. (1) The attorney general may enforce [sections 1 through
11 6].

12 (2) The attorney general may initiate a civil enforcement action against a person for violation of
13 [sections 1 through 6].

14 (3) In an action to enforce [sections 1 through 6], the attorney general may recover:

15 (a) actual damages to the consumer;

16 (b) costs;

17 (c) reasonable attorney fees; and

18 (d) \$2,500 for each violation of [section 4].

19

20 NEW SECTION. Section 7. Codification instruction. [Sections 1 through 6] are intended to be
21 codified as an integral part of Title 30, and the provisions of Title 30 apply to [sections 1 through 6].

22 - END -

SENATE BILL NO. 351

INTRODUCED BY D. ZOLNIKOV

A BILL FOR AN ACT ENTITLED: "AN ACT REVISING LAWS RELATED TO BIOMETRIC PRIVACY;
CREATING THE GENETIC INFORMATION PRIVACY ACT; REQUIRING ~~A COMPANY~~ AN ENTITY TO
PROVIDE CONSUMER INFORMATION REGARDING THE COLLECTION, USE, AND DISCLOSURE OF
GENETIC DATA; PROVIDING FOR LIMITATIONS AND EXCLUSIONS; PROVIDING FOR ENFORCEMENT
AUTHORITY; AND PROVIDING DEFINITIONS."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. Section 1. Short title. [Sections 1 through 6] may be cited as the "Genetic
Information Privacy Act".

NEW SECTION. Section 2. Definitions. As used in [sections 1 through 6], unless the context clearly
indicates otherwise, the following definitions apply:

(1) "Biological sample" means any human material ~~known~~ KNOWN to contain DNA, including tissue,
blood, urine, or saliva.

~~(2) — (a) " Company " means an entity that:~~

~~(i) — offers consumer genetic testing products or services directly to a consumer; or~~

~~(ii) — collects, uses, or analyzes genetic data that resulted from a direct-to-consumer genetic testing
product or service and was provided to the company by a consumer FOR A COMMERCIAL PURPOSE .~~

~~(b) — The term does not include an entity when it is engaged only in collecting, using, or analyzing
genetic data or biological samples in the context of research as defined in 45 CFR 164.501 conducted in
accordance with the federal policy for the protection of human research subjects under 45 CFR, part 46, the
good clinical practice guideline issued by the international council for harmonisation of technical requirements
for pharmaceuticals for human use, or the United States food and drug administration policy for the protection
of human subjects under 21 CFR, parts 50 and 56 .~~

~~(3)~~(2) "Consumer" means an individual who is a resident of this state.

~~(4)~~ "Deidentified data" means data that:

~~(a)~~ cannot be reasonably linked to an identifiable individual; and

~~(b)~~ is possessed by a company that:

~~(i)~~ takes administrative and technical measures to ensure that the data cannot be associated with a particular consumer;

~~(ii)~~ makes a public commitment to maintain and use data in deidentified form and to not attempt to reidentify data; and

~~(iii)~~ enters a legally enforceable contractual obligation that prohibits a recipient of the data from attempting to reidentify the data.

~~(5)~~(3) "DNA" means deoxyribonucleic acid.

~~(4)~~ "ENTITY" MEANS A PARTNERSHIP, CORPORATION, ASSOCIATION, OR PUBLIC OR PRIVATE ORGANIZATION OF ANY CHARACTER THAT:

~~(A)~~ OFFERS CONSUMER GENETIC TESTING PRODUCTS OR SERVICES DIRECTLY TO A CONSUMER; OR

~~(B)~~ COLLECTS, USES, OR ANALYZES GENETIC DATA.

~~(6)~~(5) "Express consent" means a consumer's affirmative response to a clear, meaningful, and prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose.

~~(7)~~(6) (a) "Genetic data" means any data, regardless of format, concerning a consumer's genetic characteristics.

(b) The term includes but is not limited to:

(i) raw sequence data that result from sequencing all or a portion of a consumer's extracted DNA;

(ii) genotypic and phenotypic information obtained from analyzing a consumer's raw sequence data; and

(iii) self-reported health information regarding a consumer's health conditions that the consumer provides to a company AN ENTITY that the company ENTITY:

(A) uses for scientific research or product development; and

(B) analyzes in connection with the consumer's raw sequence data.

~~(c)~~ The term does not include deidentified data.

(8)(7) "Genetic testing" means:

(a) a laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or gene products to determine the presence of genetic characteristics of a consumer; or

(b) an interpretation of a consumer's genetic data.

(8) "GOVERNMENTAL AGENCY" MEANS AN EXECUTIVE, LEGISLATIVE, OR JUDICIAL AGENCY, DEPARTMENT, BOARD, COMMISSION, AUTHORITY, INSTITUTION, OR INSTRUMENTALITY OF THE FEDERAL GOVERNMENT OR OF A STATE OR OF A COUNTY, MUNICIPALITY, OR OTHER POLITICAL SUBDIVISION OF A STATE.

(9) "Person" means an individual, partnership, corporation, association, business, business trust, or legal representative of an organization.

(10) "PROCESSOR" MEANS A PERSON THAT PROCESSES GENETIC DATA ON BEHALF OF AN ENTITY PURSUANT TO A CONTRACT BETWEEN THE ENTITY AND THE PROCESSOR THAT PROHIBITS THE PROCESSOR FROM RETAINING, USING, OR DISCLOSING THE GENETIC DATA, OR ANY INFORMATION REGARDING THE IDENTITY OF THE CONSUMER, INCLUDING WHETHER THAT CONSUMER HAS SOLICITED OR RECEIVED GENETIC TESTING, AS APPLICABLE, FOR ANY PURPOSE OTHER THAN FOR THE SPECIFIC PURPOSE OF PERFORMING THE SERVICES SPECIFIED IN THE CONTRACT.

(11) "THIRD PARTY" MEANS A PERSON OTHER THAN THE CONSUMER, ENTITY, OR PROCESSOR.

NEW SECTION. Section 3. ~~Limitations~~ EXCEPTIONS. (1) [Sections 1 through 6] do not apply to:

(A) protected health information that is collected by a covered entity or business associate as those terms are defined in 45 CFR, parts 160 and 164, IF SEPARATE INFORMED CONSENT RELATED TO THE COLLECTION, USE, AND DISSEMINATION OF GENETIC DATA IS OBTAINED FROM THE CONSUMER, PARENT, GUARDIAN, OR POWER OF ATTORNEY, AND THE COVERED ENTITY OR BUSINESS ASSOCIATE FOLLOWS THE POLICIES UNDER [SECTIONS 4(6)(A) THROUGH (6)(D)];

(B) AN ENTITY WHEN IT IS ENGAGED ONLY IN COLLECTING, USING, OR ANALYZING GENETIC DATA OR BIOLOGICAL SAMPLES IN THE CONTEXT OF RESEARCH AS DEFINED IN 45 CFR 164.501 CONDUCTED WITH THE EXPRESS CONSENT OF AN INDIVIDUAL AND IN ACCORDANCE WITH:

(i) THE FEDERAL POLICY FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS UNDER 45 CFR, PART 46, THE GOOD CLINICAL PRACTICE GUIDELINE ISSUED BY THE INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE; OR

(ii) THE UNITED STATES FOOD AND DRUG ADMINISTRATION POLICY FOR THE PROTECTION OF HUMAN
SUBJECTS UNDER 21 CFR, PARTS 50 AND 56; OR
(c) USES BY A GOVERNMENTAL AGENCY.
(2) BEGINNING JUNE 1, 2025, ANY COLLECTION, STORAGE, USE, OR DISSEMINATION OF GENETIC DATA BY
A GOVERNMENTAL AGENCY MUST BE PERFORMED IN ACCORDANCE WITH A SPECIFIC STATE LAW OR EXECUTED THROUGH
A SEARCH WARRANT.

NEW SECTION. Section 4. Consumer genetic data -- privacy notice -- consent -- access --
deletion -- destruction. To safeguard the privacy, confidentiality, security, and integrity of a consumer's
genetic data, ~~a company~~ AN ENTITY shall:

(1) provide clear and complete information regarding the ~~company's~~ ENTITY'S policies and
procedures for the collection, use, or disclosure of genetic data by making available to a consumer:

(a) a high-level privacy policy overview that includes basic, essential information about the
~~company's~~ ENTITY'S collection, use, or disclosure of genetic data; and

(b) a prominent, publicly available privacy notice that includes, at a minimum, information about the
~~company's~~ ENTITY'S data collection, consent, use, access, disclosure, transfer, security, and retention and
deletion practices FOR GENETIC DATA;

(2) obtain ~~a consumer's~~ initial express consent FROM A CONSUMER, PARENT, GUARDIAN, OR POWER OF
ATTORNEY for the collection, use, or disclosure of the consumer's genetic data that:

(a) clearly describes the ~~company's~~ ENTITY'S use of the genetic data that the ~~company~~ ENTITY
collects through the ~~company's~~ ENTITY'S genetic testing product or service;

(b) specifies THE CATEGORIES OF INDIVIDUALS WITHIN THE ENTITY THAT HAVE ~~who has~~ access to test
results; and

(c) specifies how the ~~company~~ ENTITY may share the genetic data;

(3) if the ~~company~~ ENTITY engages in any of the following, obtain a consumer's:

(a) separate express consent for:

(i) the transfer or disclosure of the consumer's genetic data OR BIOLOGICAL SAMPLE to any ~~person~~
THIRD PARTY other than the ~~company's vendors and service providers~~ ENTITY'S PROCESSORS, INCLUDING THE

1 NAME OF THE THIRD PARTY TO WHICH THE CONSUMER'S GENETIC DATA OR BIOLOGICAL SAMPLE WILL BE TRANSFERRED

2 OR DISCLOSED WITH THE CONSUMER'S EXPRESS CONSENT;

3 (ii) the use of genetic data beyond the primary purpose of the ~~company's~~ ENTITY'S genetic testing
4 product or service and inherent contextual uses; or

5 (iii) the ~~company's~~ ENTITY'S retention of any biological sample provided by the consumer following
6 the ~~company's~~ ENTITY'S completion of the initial testing service requested by the consumer;

7 (b) informed EXPRESS consent ~~in accordance with the federal policy for the protection of human~~
8 ~~research subjects under 45 CFR, part 46,~~ for transfer or disclosure of the consumer's genetic data to third party
9 persons for:

10 (i) research purposes; or

11 (ii) research conducted under the control of the ~~company~~ ENTITY for the purpose of publication or
12 generalizable knowledge; and

13 (c) express consent for:

14 (i) marketing to a consumer based on the consumer's genetic data; ~~or~~

15 (ii) marketing by a third-party person to a consumer based on the consumer having ordered or
16 purchased a genetic testing product or service. Marketing does not include the provision of customized content
17 or offers on the websites or through the applications or services provided by the ~~company~~ ENTITY with the first-
18 party relationship to the ~~customer~~ CONSUMER; OR

19 (III) SALE OR OTHER VALUABLE CONSIDERATION OF THE CONSUMER'S GENETIC DATA.

20 (4) comply with the provisions of 44-6-104 requiring a valid legal process for disclosing genetic
21 data to law enforcement or any other government agency without a consumer's express ~~written~~ consent;

22 (5) develop, implement, and maintain a comprehensive security program to protect a consumer's
23 genetic data against unauthorized access, use, or disclosure; and

24 (6) provide a process for a consumer to:

25 (a) access the consumer's genetic data;

26 (b) delete the consumer's genetic data; ~~and~~

27 (C) REVOKE ANY CONSENT PROVIDED BY THE CONSUMER; AND

28 ~~(e)(D)~~ request and obtain the destruction of the consumer's biological sample.

~~(7) GENETIC DATA OF MONTANA RESIDENTS OR BIOMETRIC DATA COLLECTED IN THE STATE MUST BE STORED WITHIN THE TERRITORIAL BOUNDARIES OF THE UNITED STATES. GENETIC DATA AND BIOMETRIC SAMPLES OF MONTANA RESIDENTS COLLECTED IN THE STATE MAY NOT BE STORED WITHIN THE TERRITORIAL BOUNDARIES OF ANY COUNTRY CURRENTLY SANCTIONED IN ANY WAY BY THE UNITED STATES OFFICE OF FOREIGN ASSET CONTROL OR DESIGNATED AS A FOREIGN ADVERSARY UNDER 15 CFR 7.4(A). GENETIC DATA OR BIOMETRIC DATA OF MONTANA RESIDENTS COLLECTED IN THE STATE MAY ONLY BE TRANSFERRED OR STORED OUTSIDE THE UNITED STATES WITH THE CONSENT OF THE RESIDENT.~~

NEW SECTION. Section 5. Disclosure -- when prohibited -- when ~~written~~ EXPRESS consent required. (1) The disclosure of genetic data pursuant to [sections 1 through 6] must comply with all state and federal laws for the protection of privacy and security.

~~(2) [Sections 1 through 6] may not apply to protected health information that is collected by a covered entity or business associate governed by the privacy, security, and breach notification rules issued by the:~~

~~(a) United States department of health and human services, 45 CFR, parts 160 and 164, established pursuant to the federal Health Insurance Portability and Accountability Act of 1996; and~~

~~(b) federal Health Information Technology for Economic and Clinical Health Act of 2009 .~~

~~(3)(2)~~ Notwithstanding any other provisions in [section 4], ~~a company~~ AN ENTITY ~~may~~ HAS THE SOLE AUTHORITY TO MAY not disclose a consumer's genetic data to any entity offering health insurance, life insurance, or long-term care insurance, or to any employer of the consumer without the consumer's ~~written~~ EXPRESS consent.

NEW SECTION. Section 6. Enforcement. (1) The attorney general ~~may~~ HAS THE SOLE AUTHORITY TO enforce [sections 1 through 6].

(2) The attorney general may initiate a civil enforcement action against a person for violation of [sections 1 through 6].

(3) In an action to enforce [sections 1 through 6], the attorney general may recover:

(a) actual damages to the consumer;

- 1 (b) costs;
2 (c) reasonable attorney fees; and
3 (d) \$2,500 for each violation of [section 4].

4

5 NEW SECTION. **Section 7. Codification instruction.** [Sections 1 through 6] are intended to be
6 codified as an integral part of Title 30, and the provisions of Title 30 apply to [sections 1 through 6].

7

- END -



2023 Session

Additional Senate Documents

- Business Report
- Roll Call -Attendance
- Standing Committee Reports
- Tabled Bills
- Fiscal Reports [if any]
- Roll Call Votes
- Proxies signed in ink
- Visitor's sign-in sheet.
- Informational Item's
- Witness Statements if any,
- Zoom/Internet Testimony Information & index
- Any other type of documents such as:
 - @ Petitions, {if any} Emails, all documents given to Committee Secretary before & after meeting.
- Public Testimony documents may or may not be scanned, they will be on file at the Montana Historical Society.
- Disclaimer: within the online minutes document you will see vacate spaces within the document. The LAWS II system creates these blank areas they are not loss of information.

The original exhibit/items are on file at the Montana Historical Society and may be viewed there.

Montana Historical Society Archives,
225 N. Roberts, Helena, MT 59620-1201
E-Document Specialist Susie Hamilton

**BUSINESS REPORT
MONTANA SENATE
REGULAR**

Conference Committee on SB 351

Date: 05/01/2023

Time: 10:00 AM

Place: Capitol

Room: 335

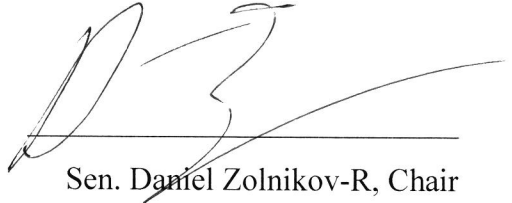
BILLS and RESOLUTIONS HEARD:

EXECUTIVE ACTION TAKEN:

SB 351:

SB 351 Accepted as Amended

Comments:



Sen. Daniel Zolnikov-R, Chair

Senate

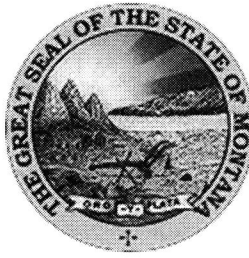
Roll Call

Conference Committee on SB 351

DATE: 05/01/2023

TIME: 10:00 AM

<u>NAME</u>	<u>PRESENT</u>	<u>ABSENT/EXCUSED</u>
Zolnikov, Daniel	X	
Bogner, Kenneth	X	
Olsen, Andrea		X
Zolnikov, Katie	X	
Hinkle, Caleb	X	
Sullivan, Katie	X	



CONFERENCE COMMITTEE
On House amendments to Senate Bill 351
Report No. 001, May 01, 2023

page 1 of 1

Mr. President and Mr. Speaker:

We, your Conference Committee met and considered House amendments to **Senate Bill 351** (reference copy-salmon) and recommended this Conference Committee be adopted.

For the Senate:

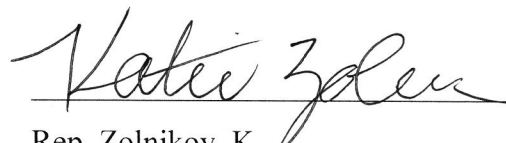

Chair Zolnikov

Sen. Olsen (Excused)

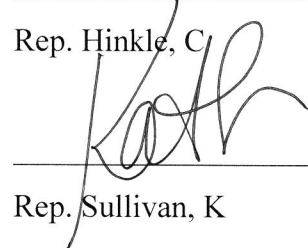

Sen. Bogner

Amendment coordinator

For the House:


Rep. Zolnikov, K


Rep. Hinkle, C


Rep. Sullivan, K

And, recommend that **Senate Bill 351** (reference copy-salmon) be **Accepted as Amended**.

ADOPT
REJECT

Amendment # Senate Bill 351001

**Amendment - Reference-white - Requested by: Daniel Zolnikov - Free Conference Committee
on SB 351**

- 2023

68th Legislature 2023

Drafter: Erin Sullivan, 406-444-3594

SB0351.003.004

SENATE BILL NO. 351

INTRODUCED BY D. ZOLNIKOV

A BILL FOR AN ACT ENTITLED: "AN ACT REVISING LAWS RELATED TO BIOMETRIC PRIVACY;
CREATING THE GENETIC INFORMATION PRIVACY ACT; REQUIRING ~~A COMPANY~~ AN ENTITY TO
PROVIDE CONSUMER INFORMATION REGARDING THE COLLECTION, USE, AND DISCLOSURE OF
GENETIC DATA; PROVIDING FOR LIMITATIONS AND EXCLUSIONS; PROVIDING FOR ENFORCEMENT
AUTHORITY; AND PROVIDING DEFINITIONS."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. Section 1. Short title. [Sections 1 through 6] may be cited as the "Genetic
Information Privacy Act".

NEW SECTION. Section 2. Definitions. As used in [sections 1 through 6], unless the context clearly
indicates otherwise, the following definitions apply:

(1) "Biological sample" means any human material ~~known~~ known to contain DNA, including tissue,
blood, urine, or saliva.

(2) ~~(a) "Company" means an entity that:~~
~~(i) offers consumer genetic testing products or services directly to a consumer; or~~
~~(ii) collects, uses, or analyzes genetic data that resulted from a direct-to-consumer genetic testing~~
~~product or service and was provided to the company by a consumer FOR A COMMERCIAL PURPOSE.~~

~~(b) The term does not include an entity when it is engaged only in collecting, using, or analyzing~~
~~genetic data or biological samples in the context of research as defined in 45 CFR 164.501 conducted in~~
~~accordance with the federal policy for the protection of human research subjects under 45 CFR, part 46, the~~
~~good clinical practice guideline issued by the international council for harmonisation of technical requirements~~
~~for pharmaceuticals for human use, or the United States food and drug administration policy for the protection~~

**Amendment - Reference-white - Requested by: Daniel Zolnikov - Free Conference Committee
on SB 351**

- 2023

68th Legislature 2023

Drafter: Erin Sullivan, 406-444-3594

SB0351.003.004

1 ~~of human subjects under 21 CFR, parts 50 and 56.~~

2 ~~(3)(2)~~ "Consumer" means an individual who is a resident of this state.

3 ~~(4) "Deidentified data" means data that:~~

4 ~~(a) cannot be reasonably linked to an identifiable individual; and~~

5 ~~(b) is possessed by a company that:~~

6 ~~(i) takes administrative and technical measures to ensure that the data cannot be associated with~~
7 ~~a particular consumer;~~

8 ~~(ii) makes a public commitment to maintain and use data in deidentified form and to not attempt to~~
9 ~~reidentify data; and~~

10 ~~(iii) enters a legally enforceable contractual obligation that prohibits a recipient of the data from~~
11 ~~attempting to reidentify the data.~~

12 ~~(5)(3)~~ "DNA" means deoxyribonucleic acid.

13 ~~(4) "Entity" means a partnership, corporation, association, or public or private organization of any~~
14 ~~character that:~~

15 ~~(a) offers consumer genetic testing products or services directly to a consumer; or~~

16 ~~(b) collects, uses, or analyzes genetic data.~~

17 ~~(6)(5)~~ "Express consent" means a consumer's affirmative response to a clear, meaningful, and
18 prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose.

19 ~~(7)(6)~~ (a) "Genetic data" means any data, regardless of format, concerning a consumer's genetic
20 characteristics.

21 (b) The term includes but is not limited to:

22 (i) raw sequence data that result from sequencing all or a portion of a consumer's extracted DNA;

23 (ii) genotypic and phenotypic information obtained from analyzing a consumer's raw sequence
24 data; and

25 (iii) self-reported health information regarding a consumer's health conditions that the consumer
26 provides to ~~a company an entity~~ that the ~~company entity~~:

27 (A) uses for scientific research or product development; and

Amendment - Reference-white - Requested by: Daniel Zolnikov - Free Conference Committee on SB 351

- 2023

68th Legislature 2023

Drafter: Erin Sullivan, 406-444-3594

SB0351.003.004

(B) analyzes in connection with the consumer's raw sequence data.

~~(c) The term does not include deidentified data.~~

~~(8)(7)~~ "Genetic testing" means:

(a) a laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or gene products to determine the presence of genetic characteristics of a consumer; or

(b) an interpretation of a consumer's genetic data.

(8) "Governmental agency" means an executive, legislative, or judicial agency, department, board, commission, authority, institution, or instrumentality of the federal government or of a state or of a county, municipality, or other political subdivision of a state.

(9) "Person" means an individual, partnership, corporation, association, business, business trust, or legal representative of an organization.

(10) "Processor" means a person that processes genetic data on behalf of an entity pursuant to a contract between the entity and the processor that prohibits the processor from retaining, using, or disclosing the genetic data, or any information regarding the identity of the consumer, including whether that consumer has solicited or received genetic testing, as applicable, for any purpose other than for the specific purpose of performing the services specified in the contract.

(11) "Third party" means a person other than the consumer, entity, or processor.

NEW SECTION. Section 3. Limitations Exceptions. (1) [Sections 1 through 6] do not apply to:

(a) protected health information that is collected by a covered entity or business associate as those terms are defined in 45 CFR, parts 160 and 164, if separate informed consent related to the collection, use, and dissemination of genetic data is obtained from the consumer, parent, guardian, or power of attorney, and the covered entity or business associate follows the policies under [sections 4(6)(a) through (6)(d)];

(b) an entity when it is engaged only in collecting, using, or analyzing genetic data or biological samples in the context of research as defined in 45 CFR 164.501 conducted with the express consent of an individual and in accordance with:

(i) the federal policy for the protection of human research subjects under 45 CFR, part 46, the

**Amendment - Reference-white - Requested by: Daniel Zolnikov - Free Conference Committee
on SB 351**

- 2023

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Drafter: Erin Sullivan, 406-444-3594

SB0351.003.004

1 good clinical practice guideline issued by the international council for harmonisation of technical requirements

2 for pharmaceuticals for human use; or

3 (ii) the United States food and drug administration policy for the protection of human subjects

4 under 21 CFR, parts 50 and 56; or

5 (c) uses by a governmental agency.

6 (2) Beginning June 1, 2025, any collection, storage, use, or dissemination of genetic data by a
7 governmental agency must be performed in accordance with a specific state law or executed through a search
8 warrant.

9
10 **NEW SECTION. Section 4. Consumer genetic data – privacy notice – consent – access –**

11 **deletion – destruction.** To safeguard the privacy, confidentiality, security, and integrity of a consumer's
12 genetic data, ~~a company~~ an entity shall:

13 (1) provide clear and complete information regarding the ~~company's~~ entity's policies and
14 procedures for the collection, use, or disclosure of genetic data by making available to a consumer:

15 (a) a high-level privacy policy overview that includes basic, essential information about the
16 ~~company's~~ entity's collection, use, or disclosure of genetic data; and

17 (b) a prominent, publicly available privacy notice that includes, at a minimum, information about the
18 ~~company's~~ entity's data collection, consent, use, access, disclosure, transfer, security, and retention and
19 deletion practices for genetic data;

20 (2) obtain ~~a consumer's~~ initial express consent from a consumer, parent, guardian, or power of
21 attorney for the collection, use, or disclosure of the consumer's genetic data that:

22 (a) clearly describes the ~~company's~~ entity's use of the genetic data that the ~~company~~ entity collects
23 through the ~~company's~~ entity's genetic testing product or service;

24 (b) specifies the categories of individuals within the entity that have ~~who has~~ access to test results;

25 and

26 (c) specifies how the ~~company~~ entity may share the genetic data;

27 (3) if the ~~company~~ entity engages in any of the following, obtain a consumer's:

**Amendment - Reference-white - Requested by: Daniel Zolnikov - Free Conference Committee
on SB 351**

- 2023

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Drafter: Erin Sullivan, 406-444-3594

SB0351.003.004

1 (a) separate express consent for:

2 (i) the transfer or disclosure of the consumer's genetic data or biological sample to any ~~person~~
3 third party other than the ~~company's vendors and service providers~~ entity's processors, including the name of
4 the third party to which the consumer's genetic data or biological sample will be transferred or disclosed with
5 the consumer's express consent;

6 (ii) the use of genetic data beyond the primary purpose of the ~~company's entity's~~ genetic testing
7 product or service and inherent contextual uses; or

8 (iii) the ~~company's entity's~~ retention of any biological sample provided by the consumer following
9 the ~~company's entity's~~ completion of the initial testing service requested by the consumer;

10 (b) informed express consent ~~in accordance with the federal policy for the protection of human~~
11 ~~research subjects under 45 CFR, part 46,~~ for transfer or disclosure of the consumer's genetic data to third party
12 persons for:

13 (i) research purposes; or

14 (ii) research conducted under the control of the ~~company entity~~ for the purpose of publication or
15 generalizable knowledge; and

16 (c) express consent for:

17 (i) marketing to a consumer based on the consumer's genetic data; ~~or~~

18 (ii) marketing by a third-party person to a consumer based on the consumer having ordered or
19 purchased a genetic testing product or service. Marketing does not include the provision of customized content
20 or offers on the websites or through the applications or services provided by the ~~company entity~~ with the first-
21 party relationship to the ~~customer consumer;~~ or

22 (iii) sale or other valuable consideration of the consumer's genetic data.

23 (4) comply with the provisions of 44-6-104 requiring a valid legal process for disclosing genetic
24 data to law enforcement or any other government agency without a consumer's express ~~written~~ consent;

25 (5) develop, implement, and maintain a comprehensive security program to protect a consumer's
26 genetic data against unauthorized access, use, or disclosure; and

27 (6) provide a process for a consumer to:

**Amendment - Reference-white - Requested by: Daniel Zolnikov - Free Conference Committee
on SB 351**

- 2023

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Drafter: Erin Sullivan, 406-444-3594

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(a) access the consumer's genetic data;

(b) delete the consumer's genetic data; ~~and~~

~~(c) revoke any consent provided by the consumer; and~~

~~(e)(d)~~ request and obtain the destruction of the consumer's biological sample.

~~(7) GENETIC DATA OF MONTANA RESIDENTS OR BIOMETRIC DATA COLLECTED IN THE STATE MUST BE~~

~~STORED WITHIN THE TERRITORIAL BOUNDARIES OF THE UNITED STATES. Genetic data and biometric samples of~~

~~Montana residents collected in the state may not be stored within the territorial boundaries of any country~~

~~currently sanctioned in any way by the United States office of foreign asset control or designated as a foreign~~

~~adversary under 15 CFR 7.4(a). Genetic data or biometric data of Montana residents collected in the state may~~

~~only be transferred or stored outside the United States with the consent of the resident.~~

NEW SECTION. Section 5. Disclosure -- when prohibited -- when ~~written express~~ consent

required. (1) The disclosure of genetic data pursuant to [sections 1 through 6] must comply with all state and federal laws for the protection of privacy and security.

~~(2) [Sections 1 through 6] may not apply to protected health information that is collected by a covered entity or business associate governed by the privacy, security, and breach notification rules issued by the:~~

~~(a) United States department of health and human services, 45 CFR, parts 160 and 164, established pursuant to the federal Health Insurance Portability and Accountability Act of 1996; and~~

~~(b) federal Health Information Technology for Economic and Clinical Health Act of 2009.~~

~~(3)(2)~~ Notwithstanding any other provisions in [section 4], ~~a company an entity may~~ **HAS THE SOLE AUTHORITY TO MAY** not disclose a consumer's genetic data to any entity offering health insurance, life insurance, or long-term care insurance, or to any employer of the consumer without the consumer's ~~written express~~ consent.

NEW SECTION. Section 6. Enforcement. (1) The attorney general ~~may has the sole authority to~~ enforce [sections 1 through 6].

**Amendment - Reference-white - Requested by: Daniel Zolnikov - Free Conference Committee
on SB 351**

- 2023

68th Legislature 2023

Drafter: Erin Sullivan, 406-444-3594

SB0351.003.004

1 (2) The attorney general may initiate a civil enforcement action against a person for violation of
2 [sections 1 through 6].

3 (3) In an action to enforce [sections 1 through 6], the attorney general may recover:

4 (a) actual damages to the consumer;

5 (b) costs;

6 (c) reasonable attorney fees; and

7 (d) \$2,500 for each violation of [section 4].

8

9 **NEW SECTION. Section 7. Codification instruction.** [Sections 1 through 6] are intended to be
10 codified as an integral part of Title 30, and the provisions of Title 30 apply to [sections 1 through 6].

11

- END -

VISITORS REGISTER
MONTANA SENATE
FREE CONFERENCE COMMITTEE SB351
May 1, 2023

NAME	REPRESENTING	Support	Oppose	Informat'l

Please leave prepared testimony with Committee Secretary.